

accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published in 42 CFR part 498.

(1) References to the Health Care Financing Administration (HCFA) in 42 CFR part 498 should be read as the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health, Food and Drug Administration.

(2) References to the Appeals Council of the Social Security Administration in 42 CFR part 498 should be read as references to the Departmental Appeals Board.

(3) In accordance with the procedures set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP.

(i) A facility must request reconsideration by DMQRP within 60 days of the accreditation body's adverse appeals decision, at the following address: Division of Mammography Quality and Radiation Programs (HFZ-240), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, Attn: Facility Accreditation Review Committee.

(ii) The request for reconsideration shall include three copies of the following records:

(A) The accreditation body's original denial of accreditation.

(B) All information the facility submitted to the accreditation body as part of the appeals process;

(C) A copy of the accreditation body's adverse appeals decision; and

(D) A statement of the basis for the facility's disagreement with the accreditation body's decision.

(iii) DMQRP will conduct its reconsideration in accordance with the procedures set forth in subpart B of 42 CFR part 498.

(4) A facility that is dissatisfied with DMQRP's decision following reconsideration is entitled to a formal hearing in accordance with procedures set forth in subpart D of 42 CFR part 498.

(5) Either the facility or FDA may request review of the hearing officer's decision. Such review will be conducted by the Departmental Appeals Board in accordance with subpart E of 42 CFR part 498.

(6) A facility cannot perform mammography services while an adverse accreditation decision is being appealed.

§ 900.16 Appeals of denials of certification.

(a) The appeals procedures described in this section are available only to facilities that are denied certification by FDA after they have been accredited by an approved accreditation body. Appeals for facilities that have failed to become accredited are governed by the procedures set forth in § 900.15.

(b) FDA may deny the application if the agency has reason to believe that:

(1) The facility will not be operated in accordance with standards established under § 900.12;

(2) The facility will not permit inspections or provide access to records or information in a timely fashion; or

(3) The facility has been guilty of misrepresentation in obtaining the accreditation.

(c)(1) If FDA denies an application for certification by a facility that has received accreditation from an approved accreditation body, FDA shall provide the facility with a statement of the grounds on which the denial is based.

(2) A facility that has been denied accreditation may request reconsideration and appeal of FDA's determination in accordance with the applicable provisions of § 900.15(d).

§ 900.17 [Reserved]

§ 900.18 Alternative requirements for § 900.12 quality standards.

(a) *Criteria for approval of alternative standards.* Upon application by a qualified party as defined in paragraph (b) of this section, FDA may approve an alternative to a quality standard under § 900.12, when the agency determines that:

(1) The proposed alternative standard will be at least as effective in assuring quality mammography as the standard it proposes to replace, and

(2) The proposed alternative: